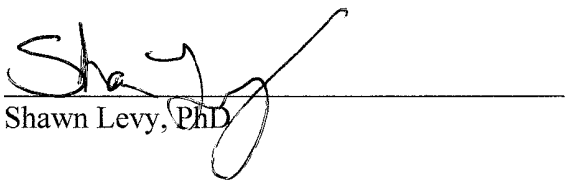
EXHIBIT C39

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION ***THIS DOCUMENT RELATES TO ALL CASES***	**MDL NO. 16-2738 (FLW) (LHG)**

RULE 26 EXPERT REPORT OF SHAWN LEVY, PHD

Date: November 16, 2018



Shawn Levy, PhD

I. Qualifications and Background

I am a founding director of and a faculty investigator with the Genomic Services Laboratory at the HudsonAlpha Institute for Biotechnology. My focus is on use of high performance genotyping and sequencing technologies as support for plant and animal phylogenetic studies and translational and clinical-based projects. A portion of my research entails using whole-genome sequencing to identify genetic markers associated with specific health conditions.

I serve as executive director of the HudsonAlpha Clinical Services Laboratory, LLC, which I launched in 2014. I am adjunct faculty in the department of genetics and department of epidemiology at the University of Alabama at Birmingham, adjunct faculty in the department of biological Sciences at the University of Alabama at Huntsville, and serve as an ad hoc reviewer for scientific journals including Nature, Nature Genetics, Science, Cell, Genome Research and several others. I have been a co-chair of the Genomics Working Group of the American Medical Informatics Association, a community of scientists and health care professionals that work to facilitate collaboration and share knowledge across a continuum, from basic and applied research to the consumer and public health arenas.

Prior to joining HudsonAlpha in 2009, I was a faculty member at Vanderbilt University Medical Center with appointments in the Department of Molecular Physiology and Biophysics and the Department of Biomedical Informatics. I was the founding director of the Vanderbilt Microarray Shared Resource where I served as Director for 9 years. I received my PhD in biochemistry and completed a postdoctoral fellowship in genetics at Emory University in Atlanta, where I set up a microarray facility at the Emory Center for Molecular Medicine. My education, training, and experience are further set forth in my Curriculum Vitae (CV), which is attached to this report as **Exhibit A**.

As detailed in my CV, my research activities have examined a number of basic questions in human cancer such as the role of viral infection in head and neck cancer, the role of genetic mutation in risk for secondary cancer events following initial treatment, the genetics of B-cell

lymphoma, hepatosplenic T-cell lymphoma and malignant melanoma, and the role of STAT3 in triple-negative breast cancer. As the founding and Executive Director of the HudsonAlpha Clinical Services Laboratory, I also have interests and responsibilities in the clinical use of genetic testing for cancer risk and treatment stratification. HudsonAlpha launched the Information is Power campaign and has provided genetic testing for breast and ovarian cancer risk to women across the state of Alabama free of charge. My lab has also supported the Alabama Genomics Health Initiative that tests for genetic risks and carrier status for a number of diseases, including breast and ovarian cancer. This body of work in basic and clinical research in combination with earlier epidemiological work in the Shanghai Women's Health study provides the experience, education and expertise to develop this report.

I have been retained to describe the role of genetics in the pathogenesis of cancer in general and specifically ovarian cancer. Further, I have been asked to assess whether perineal use of talcum powder products induces a biologically plausible mechanism or mechanisms that result in ovarian cancer.

My report consists of a review and my conclusions regarding this cause-and-effect relationship. My opinions are based on my assessing and weighing the totality of the evidence, including relevant literature and available documentation, and my experience as a geneticist and scientific researcher. Report references are listed at the end of this report, and a more comprehensive list of the documents and materials reviewed prior to formulating the opinion in this report is attached as **Exhibit B**. The methodology that I have used to reach my opinions in this case is generally accepted in the scientific community and is the same methodology that I use in my research and other professional activities. All of my opinions stated below are held to a reasonable degree of scientific certainty. My opinions reflect my sole and independent judgment at the time of this report.

My billing rate is $500 per hour. I have not testified by deposition or at trial during the last four years.

II. Cancer Overview

Cancer has become a descriptor that is ubiquitously used but describes an extremely complex and diverse collection of medical conditions. Cancer is also a word that represents an amazingly complicated and often misunderstood collection of diseases. At the most basic level, cancer can be described as a disease of unregulated cell growth but its simplicities end with that simple description. From the moment of conception until death, humans experience an unending cycle of cell growth, differentiation and death. As infants grow to children and then to adults, there are an array of growth processes that occur that represent the milestones of development and maturation. These processes are an orchestra of highly coordinated and regulated events with important checks and balances. When those highly regulated processes are defective or the checks and balances malfunction, the growth of the cells can become unregulated. Which tissue or cells become unregulated and exactly what process is defective defines the type of cancer and its progression. Cancer can be aggressive and highly metastatic when unregulated cells invade other parts of the body and destroy organs and tissues. Other types of cancer remain restricted to specific organs or cell types and may be less aggressive.

It is the DNA within our cells which provides the genetic code or instructions to create the cells, tissues, and organs that make a human. Subtle changes in that code lead to the diversity of people around the world, while more substantial changes in that code create the diversity of life forms around us, from the smallest bacteria to the largest plants and animals. All cells have one set of instructions that provides the information for cells to divide, tissues to grow and how cells should die.

III. The Role of Gene Mutations in the Development of Cancer

At its fundamental level, cancer is caused by changes (mutations) to the DNA within cells. The DNA that makes up our genetic code is organized into a large number of individual genes, each of which contains a specific subset of instructions telling the cell what functions to perform, as well as how to grow and divide. Errors in the instructions can cause the cell to stop its normal function and may allow a cell to become cancerous. Mutations that cause cancer most commonly

disrupt the regulation of the cell cycle (i.e., stages of cell growth and division). The following classifications of mutations are those most commonly found in cancer, but many other gene mutations can contribute to causing cancer as well.

Increasing cell growth and division. A gene mutation can initiate more rapid cell growth and division, resulting in many new cells that all have that same mutation. Proto-oncogenes are a group of genes that regulate cell growth, differentiation, division and death. When a proto-oncogene is mutated, it can become an oncogene that then instructs the cell to grow rapidly in an unregulated manner.

Loss of growth inhibition. A gene mutation can result in the renewed growth of a cell that had previously stopped growing. Normal cells regulate their division so that the human body contains the appropriate number of each type of cell. When the tumor suppressor genes that provide this inhibitory control become mutated, cells become cancer cells and continue to grow and amass. An example of one such gene is *p53*, which is discussed in more detail below.

Loss of DNA repair. Gene mutations can also affect the genes that proofread DNA and fix mutations before they can have a detrimental effect. DNA repair genes look for errors in a cell's DNA and make corrections. A mutation in a DNA repair gene may mean that other errors aren't corrected, leading cells to become cancerous through unchecked replication of damaged cells. Examples of DNA repair genes include *BRCA1* and *BRCA2* which are discussed in more detail below.

Another way of classifying gene mutations is by when they occur.

1) Inherited gene mutations: Inherited gene mutations are those mutations an individual is born with and that are present in all cells of the body. These types of mutations define traits and characteristics that have a family history. This type of mutation directly accounts for a small percentage of cancers. The indirect effects of this type of mutation is an area of active research. There are a growing number of genes and mutations that are known to increase the risk of cancer. *BRCA1* and *BRCA2* mutations and the increased risk for breast and ovarian cancer are two examples. While additional genes are being identified, the

percentage of individuals affected by mutations in those genes will be significantly less than those affected by *BRCA1* and *BRCA2*.

2) Acquired (somatic) gene mutations: Somatic mutations are acquired after birth. Most gene mutations that directly cause cancer occur after birth and aren't inherited. Gene mutations can be caused by a number of events or exposures. These include environmental exposures such as smoking, radiation, and cancer-causing chemicals (carcinogens). Biological and lifestyle exposures such as viruses, obesity, hormones, and chronic inflammation are also known to result in cancer-causing mutations. Each exposure type has its own mechanism in increasing risk for cancer. These mechanisms may be direct, such as radiation directly damaging DNA, as well as indirect, such as an external agent causing a cellular reaction or inflammatory response that then leads to DNA damage or mutation.

Both inherited and acquired gene mutations work together to cause cancer. While genetic testing has become commonplace for both assessing risk for cancer as well as directing treatment, the catalog of oncogenes, tumor suppressor genes, and DNA repair genes make genetic testing valuable and impactful for informing patients of their genetic risk for cancer. Genetic testing generally detects inherited mutations. Currently, genetic screening does not detect acquired gene mutations because they occur only in certain cells. Even if one has inherited a genetic mutation that predisposes one to cancer, that doesn't mean he or she is certain to get cancer. Rather, one or more additional gene mutations may be needed to cause cancer. The inherited gene mutation could instead make one more likely to develop cancer when exposed to a certain cancer-causing substance. Conversely, an individual may still develop cancer if they do not have mutations known to predispose one to cancer. Additionally, chemical and other environmental agents such as talcum powder products can interact with inherited mutations to cause ovarian cancer.

IV. The Role of Genetics in Ovarian Cancer

Ovarian cancer is the major cause of death from gynecologic disease and the second most common gynecologic malignancy worldwide (Nunes and Serpa, 2018; Siegel, 2015; Torre, 2015). The term “ovarian cancer” is often used to include fallopian tubal, ovarian epithelial and peritoneal

cancers since the pathogenesis, treatment and clinical courses are similar. Researchers now believe that most of these cancers originate in the distal portion of the fallopian tube (Levanon, 2008). The significant mortality is primarily associated with late diagnosis and resistance to therapy (Bowtell, 2010). Epithelial ovarian cancer (EOC) includes most malignant ovarian neoplasms (Chan, 2006) that can be classified based on morphologic and molecular genetic features into the following types: serous (OSC; low and high grade), endometrioid (EC), clear cell (OCCC) and mucinous (MC) carcinomas.

Certain specific genetic and transcriptional signatures are associated with each histological subtype. Low-grade OSC cases generally have genetic alterations in BRAF, KRAS, NRAS, and Erb-B2 Receptor Tyrosine Kinase 2 (ERBB2); high-grade OSC has mutations in Tumor Protein P53 (TP53), BRCA1/2, Neurofibromin 1 (NF1), RB Transcriptional Corepressor 1 (RB1), and Cyclin Dependent Kinase 12 (CDK12) (Chan, 2006). Homologous recombination repair of DNA damage is defective in approximately 50% of high-grade serous cancers along with alterations in signaling pathways such as PI3/Ras/Notch/ FoxM1 (Nunes and Serpa, 2018).

Endometroid carcinoma (EC) subtypes involve mutations in AT-Rich Interaction Domain 1A (ARID1A), Phosphatidylinositol-4,5-Bisphosphate 3-Kinase Catalytic Subunit Alpha (PI3KCA), Phosphatase And Tensin Homolog (PTEN), Protein Phosphatase 2 Scaffold Subunit Alpha (PPP2R1α), and mismatch repair deficiency. Ovarian clear cell carcinoma (OCCC) subtypes have been found with de novo expression of HNF1β (Mabuchi, 2009; Shen, 2013) as well as ARID1A, PI3KCA, PTEN, Catenin Beta 1 (CTNNB1) and PPP2R1α mutations. MC comprises tumors with mutations in KRAS and a high frequency of ERBB2 amplification with overexpression of mucin-coding genes (Banerjee and Kaye, 2013; Jayson, 2014).

In addition to inherited mutations, exposure to the environment can result in DNA changes, or acquired gene mutations, that lead to cancer. These sources can be from exposure to minerals such as asbestos or arsenic, chemical exposures such as benzene or formaldehyde and from natural radiation sources like radon or ultraviolet light. These exposures constantly damage human DNA. Fortunately, cells have robust DNA repair mechanisms to ensure DNA damage is repaired before the DNA is replicated. These “proofreading” mechanisms react to DNA damage and stop DNA

replication. The mechanisms involve checkpoint control proteins such as the p53 protein, which acts to stop the cell cycle if DNA is damaged, and thus to suppress production of tumors. Cells that do not express functional p53 protein exhibit high rates of mutation in response to DNA damage, accelerating the formation of tumors.

BRCA1 and BRCA2 proteins also function in the DNA repair pathway. *BRCA1* and *BRCA2* are normally expressed in the cells of breast and other tissue, where they help repair damaged DNA, or destroy cells if DNA cannot be repaired. They are involved in the repair of chromosomal damage resulting from double-strand breaks. *BRCA1* combines with other tumor suppressors, DNA damage sensors and signal transducers to form a large multi-subunit protein complex known as the BRCA1-associated genome surveillance complex (BASC). BRCA2 interacts with the RAD51 protein, also forming a complex that is vital for DNA repair.

Individuals can inherit mutations in *BRCA1*, *BRCA2* or *p53*,[1] and are termed "positive" for the gene mutation. Such mutations will detrimentally affect the ability to repair DNA or sense the presence of damaged DNA. These defects allow additional mutations to accumulate in cells and lead to a higher probability of cells becoming cancerous. *BRCA1*, *BRCA2* and *p53* mutations can also be acquired in certain cells. If those cells form a tumor, the cancerous tissue can be tested for these gene mutations.

BRCA mutations are inherited in an autosomal dominant fashion, meaning inheriting only one copy results in increased cancer risk. Some individuals with a mutation in the *BRCA1* or *BRCA2* gene will develop cancer during their lifetime, but others will not. Penetrance refers to the proportion of individuals with a genetic mutation who exhibit symptoms of the disorder. Where some carriers do not develop a disorder, as in the case of *BRCA* carriers, the condition is said to have incomplete penetrance. In such instances, additional genetic, environmental and lifestyle factors must be present for the disorder to manifest. The lifetime risk for ovarian cancer is approximately 40 percent for *BRCA1* carriers and 15 to 20 percent for *BRCA2* carriers (Berek et

[1] Genes consist of genetic information that code for functional proteins. Both the gene and the protein they code share the same alphanumeric name. To avoid confusion, genes are italicized in text and proteins are not. For example: *BRCA1* (gene) and BRCA1 (protein).

al., 2012; Paluch-Shimon et al., 2016). Therefore, the presence of mutations in the *BRCA* genes do not guarantee that carriers will get cancer. The presence of these mutations increases a person's risk of developing cancer when exposed to a carcinogen (Park, 2018; Vitonis, 2011; Wu, 2015).

Mutations in *BRCA* genes are found in the minority of epithelial ovarian cancer cases, suggesting additional mechanisms involving other genes that predispose women to ovarian cancer. The location of the mutation within the *BRCA1* and *BRCA2* genes has been associated with different ovarian cancer risk (Rebbeck, 2015). Additionally, several common alleles, or alternate forms of a gene, have been found to modify ovarian cancer risk for *BRCA1* and *BRCA2* mutation carriers. These modifier genes alter the process by which information from a gene is used to synthesize a final gene product (gene expression) in another gene, which in turn causes a disease. They are hypothesized to act as low to moderate penetrance alleles that contribute to ovarian cancer risk. (Barnes and Antoniou, 2012; Ramus, 2008; Saed, 2017; Sellers, 2008). These modifiers consist of changes in the DNA called single-nucleotide variants (SNVs), and result in a point mutation in the gene. The mutation can result in a structurally altered protein that is functionally defective. Some of the affected proteins are oxidants, antioxidants, or otherwise involved in regulatory pathways involving cancer risk, as discussed below.

Lynch syndrome is another hereditary condition that increases the risk of ovarian cancer. It is caused by mutations that impair DNA mismatch repair, and the disease is inherited in an autosomal dominant manner similar to *BRCA* mutations. As in the case of *BRCA* mutations, due to incomplete penetrance inheriting a Lynch-associated mutation does not guarantee an individual will get cancer, but rather, that the risk of cancer will increase when exposed to a carcinogen.

Myriad Genetics was an early pioneer in the development of commercial genetic testing for *BRCA1* and *BRCA2* mutations and predicting risk for breast and ovarian cancer. As with all inherited traits, a positive family history is the strongest indicator of the presence of genetic risk alleles in an individual. Since the exact identity of those risk alleles and the magnitude of cancer risk remain unknown until testing is performed, early guidelines for testing were based on a positive family history. The availability of testing has increased and costs of testing have fallen. However, genetic testing remains a relatively rare practice in the general population. Since the

early 1990s, advanced molecular biological technologies have allowed for the connection to be made between specific genetic mutations and the resulting hereditary cancers. Because of the large number of individuals tested and the ability to trace their genetic inheritance, the genes involved in cancer development are well established. In the overall spectrum, there are additional variants and genes with minor involvement, but development is dependent upon specific and complex interactions that occur in rare situations, and it is extremely unlikely any would have impact of known mutations such as *BRCA1* or *BRCA2*.

V. Response to Cellular Injury

As previously mentioned, from the moment of conception, the human body relies on continuous cell growth and development for normal health and function. Some tissues and cell types continually turn over. Our skin, blood cells, immune cells and the cells that line our digestive tract are examples where cells are continually growing and replacing older cells. In the case of an injury, a complex cascade of events begins which involves inflammation and culminates in the healing of the wound. During tissue injury, cell proliferation is enhanced while the tissue regenerates. After the healing is complete, proliferation and inflammation subside.

In contrast, proliferating cells that sustain DNA damage and/or mutagenic insult (for example, initiated cells) continue to proliferate in microenvironments rich in inflammatory cells and growth/survival factors that support their growth. In a sense, tumors act as wounds that fail to heal (Dvorak, 1986). Recent studies have shown a link between inflammation associated with wound healing and ovarian cancer cell seeding (Jia, 2018). In addition to inflammation, the innate immune response plays a role in promoting cancer development and progression. These observations are generally accepted in the scientific literature (Coussens and Werb, 2002; Pardoll, 2002).

VI. Inflammation

A. The Role of Inflammation in Cancer - General

The functional relationship of cancer and inflammation was first described in the mid-1800s. Rudolf Virchow noted leucocytes in neoplastic tissues in 1863 and made a connection between inflammation and cancer (as cited in Balkwill and Mantovani, 2001). He suggested that the "lymphoreticular infiltrate" reflected the origin of cancer at sites of chronic inflammation. Research published over the last 20 years has provided further understanding of the inflammatory microenvironment of malignant tissues and validates Virchow's hypothesis. Furthermore, the links between cancer and inflammation now have quite strong implications for prevention and treatment. (Balkwill and Mantovani, 2001).

Macrophages are versatile immune-system cells that play a variety of roles in health and well-being. They act in tissues and free-floating cells in the blood that engulf and digest cellular debris, foreign substances, infectious microbes, cancer cells and anything that does not have the correct cell surface proteins to indicate a healthy cell to the body. They take various forms with various names throughout the body and have specialized tasks, including recruiting other immune cells like lymphocytes to sites of infection or acting as antigen presenting cells to T cells. Upon activation by contact with substances foreign to the body, macrophages release small proteins called cytokines. Generally speaking, macrophages can increase inflammation or decrease inflammation depending on the cytokines released.

Tumor-associated macrophages (TAM) are a major component of the infiltrate of most, if not all, tumors (Franklin and Li, 2016). TAM derive from circulating monocytic precursors, and are directed into the tumor by chemoattractant cytokines called chemokines. Many tumor cells also produce cytokines called colony-stimulating factors that prolong survival of TAM. When appropriately activated, TAM can kill tumor cells or elicit tissue destructive reactions on the vascular endothelium to disrupt blood supply to the tumor. However, TAM also produce growth and angiogenic factors as well as protease enzymes which degrade the extracellular matrix. Therefore, TAM can stimulate tumor-cell proliferation, promote angiogenesis, and favor invasion and metastasis (Mantovani, 1992b; Mantovani, 1997). Direct evidence for the importance of

protease production by TAM, neutrophils, and mast cells during experimental carcinogenesis was reported more than 15 years ago (Coussens, 2000). Since that time, the report by Coussens at el has been cited nearly 300 times by other studies. This dual potential of TAM has been described in the literature as the "macrophage balance." (Liu and Cao, 2015; Mantovani, 1992a).

B. The Role of Inflammation in Ovarian Cancer

Inflammation has also been shown to play a key role directly in epithelial ovarian cancer. This principle is generally accepted in the scientific community and very well reviewed in the scientific literature over the last decade, as the role of inflammation is common in many types of cancer. (Charbonneau, 2013; Kisielewski, 2013; Maccio and Madeddu, 2012; Mor , 2011; Pardoll, 2002; Pejovic and Nezhat, 2011; Shan and Liu, 2009). The literature reviews, as well as many direct studies, feature the immune system as being an important mediator of ovarian carcinogenesis via two models for its role in ovarian cancer: 1) chronic inflammation and 2) incessant ovulation.

1) Chronic Inflammation: The chronic inflammation model of carcinogenesis proposes that chronic exposures to external or endogenous triggers of immunity (such as known carcinogens) and the persistence of immune cells cause ovarian cancer. These inflammatory triggers cause injury to surrounding epithelium, damage DNA through the release of reactive oxygen species (ROS), or produce cytokines that promote proliferation (Saed, 2017). One environmental exposure shown to induce inflammation in animal models and human lungs is talcum powder (Wehner, 1994). Composed primarily of magnesium silicate, talc has been linked to ovarian cancer risk in a number of studies (Ness, 2000; Mills, 2004; Merritt, 2008; Wu, 2009; Rosenblatt, 2011; Wu, 2015; Penninkilampi, 2018).

2) Incessant Ovulation: As stated in (Charbonneau, 2013), incessant ovulation results in damage due to rupturing of the ovulating follicle, which traumatizes the ovarian surface causing an immediate inflammatory response and wound repair. Repeating this process of damage and epithelial proliferation to repair the wound increases the risk of malignant transformation. Epidemiologic studies beginning nearly 50 years ago have implicated increased number of ovulations as a risk factor for ovarian cancer (Mahdavi, 2006). In

contrast, decreased risk of (i.e., protection from) ovarian cancer has been associated with increased parity (Adami, 1994; Modan, 2001), oral contraceptive use (Narod , 1998), breast feeding (Jordan, 2012) and older age at first menses (Titus-Ernstoff, 2001). All of these protective factors impact the number of lifetime ovulations. One of these early studies from the late 1970's, which has been further substantiated by more recent investigations, found protective effects of "anovulatory time" by combining information on both increased oral contraceptive use and parity as well as age at first and last menses (Casagrande, 1979), supporting the theory of incessant ovulation as an underlying mechanism of carcinogenesis.

As a part of the inflammatory response, macrophages induce oxidative stress through production of reactive oxygen species (ROS) and reactive nitrogen species (RNS). Normally, oxidants and antioxidants maintain a balance wherein the amount of ROS does not overwhelm the ability of the body, and antioxidants, to regulate them. Free radicals such as ROS and RNS are highly reactive and adversely alter DNA, proteins, and lipids (which comprise cell membranes) to promote tumor development and progression, and many cancers arise from sites that are subject to chronic irritation, infection, or inflammation. Cancer cells persist in a pro-oxidant state where there is excess production and generation of ROS that allows for tumor initiation, promotion and progression.

The association between exposure to pathogens and chronic inflammation in tumor promotion and progression is further support of the generally understood principle that chronic inflammation plays a key role in the development of ovarian cancer. Examples of inflammatory conditions that are associated with ovarian cancer include endometriosis and pelvic inflammatory disease. Evidence strongly suggests that endometriosis is a pelvic inflammatory condition (Agic, 2006), and that inflammation explains the association between endometriosis and epithelial ovarian cancer (Ness, 2000). Studies have found a relationship between pelvic inflammatory disease and ovarian cancer risk (Lin, 2011; Merritt, 2008). Moreover, the effect of non-steroidal anti-inflammatory drugs (NSAIDs) to reduce the risk of ovarian cancer provides additional support. The earlier studies with a focus on NSAIDs were preliminary and results were somewhat

inconsistent (Bonovas, 2005; Merritt, 2008), but a recent pooled analysis examining 12 case-control studies found aspirin could reduce ovarian cancer risk by 20%-34% (Trabert, 2014).

Additional studies illustrate the potential protective effects of anti-inflammatory agents, including from unexpected drugs such as metformin. As reviewed in Reid, 2017, evidence supports a role for the anti-diabetic agent, metformin, in the prevention and treatment of multiple cancers (Li, 2011). Studies reviewed include a case-control study including 1,611 incident ovarian cancer cases performed using the UK-based General Practice Research Database (Bodmer, 2011). Long-term use (≥ 30 prescriptions) of metformin (and not sulfonylureas or insulin) was associated with a trend towards reduced risk with an odds ratio of 0.61. Though these results alone were not statistically significant, the reported observation that the anti-inflammatory agent, metformin, appears to decrease the risk of cancer, is additional evidence that inflammation is a primary mediator of ovarian cancer. (Irie, 2016).

Considering the well-established role that inflammation plays in cancer and the beneficial effects of anti-inflammatory compounds on cancer risk and progression, it is logical to examine the environmental factors that may directly lead to cancer or that may increase chronic inflammation and indirectly lead to cancer. The International Agency for Research on Cancer (IARC) has recognized for nearly thirty years that there is sufficient evidence to conclude human exposure to asbestos is a cause of ovarian cancer (IARC, 1987; IARC, 2012). Not surprisingly, human studies have reported asbestos fibers in ovaries (Heller, 1996; Langseth, 2007). Meta-analysis continues to support the conclusion that exposure to asbestos increases risk for ovarian cancer (Camargo et al., 2011).

C. Talcum Powder Products

A number of studies have been performed to examine the role of talcum powder use in the development of ovarian cancers. A comprehensive and recent meta-analysis by Penninkilampi found an association between perineal talc use and ovarian cancer, with a greater association after a higher number of lifetime applications (Penninkilampi and Eslick, 2017). The Penninkilampi study identified 24 case–control (13,421 cases) and three cohort studies (890 cases). Observational studies involving at least 50 cases of ovarian cancer were eligible for inclusion. Penninkilampi

analyzed the association between ovarian cancer and any perineal talc use. Included studies reported specific types of ovarian cancer, long-term (>10 year) talc use total lifetime applications, frequency and use of talc while also using diaphragms or sanitary napkins.

The Penninkilampi study found a consistent association between perineal talc use and ovarian cancer. Variation in the magnitude of the effect was found when considering study design and ovarian cancer subtype. Any perineal talc use was associated with increased risk of ovarian cancer (OR=1.31, 95%CI 1.24-1.39). Greater than 3,600 lifetime applications (OR=1.42, 95%CI 1.25-1.61) was slightly more associated with ovarian cancer than less than 3,600 applications (OR=1.32, 95%CI 1.15- 1.50).

In addition to epidemiological evidence, an *in vitro* experiment by Buz'Zard and Lau reported an increase in ROS generation, increased cell proliferation and neoplastic transformation (conversion into cancerous cells) in human ovarian cells treated with talcum powder (Buz'Zard and Lau, 2007). They also found talcum powder treatment increased the number of reactive oxygen species produced by polymorphonuclear neutrophils, inflammatory cells whose role is to release large quantities of reactive oxygen species in response to a variety of harmful foreign stimuli. Additional studies have also shown the effects of talc on the immune response (Hamilton, 1984; Keskin, 2009; NTP, 1993).

Some studies have suggested that the link between ovarian cancer and talcum powder product use may be influenced by a number of genes (Belotte, 2015; Fletcher, 2018[a]; Gates, 2008; Shukla, 2009). Gates and colleagues found that women with certain genetic variants in glutathionine S-transferase M1 (GSTM1) and/or glutathionine S-transferase T1 (GSTT1) may have a higher risk of ovarian cancer associated with talc use (Gates, 2008). In a recently peer-reviewed and accepted abstract, Harper and Saed report a mechanism by which talc enhances the pro-oxidant state in normal (ovarian and tubal) and ovarian cancer cells, through induction of gene point mutations (corresponding to known specific single nucleotide polymorphisms - SNPs) in key oxidant enzymes, altering their activities (Harper and Saed, 2018).

In a more recent study, talcum powder increased mRNA levels of pro-oxidant enzymes in normal ovarian epithelial cells and ovarian cancer cell lines, while decreasing the mRNA levels of

antioxidant enzymes (Saed et al., 2017; Saed et al., 2018). A follow-up study reported in an abstract showed epithelial ovarian cancer cells treated with talc to demonstrate increased levels of CA-125 (Fletcher, 2018[b]). CA-125 is a biomarker that has been found to be elevated in patients with ovarian cancer and is currently FDA approved for disease monitoring in patients with epithelial ovarian cancer, as well as those with BRCA mutations or who are in another in high-risk group.

D. Asbestos, Fibrous Talc, Heavy Metals and Fragrance Chemicals

In addition to the mineral talc, I have seen evidence that talcum powder products, including Johnson's Baby Powder and Shower to Shower, contain asbestos[2], and heavy metals[3] such as chromium, cobalt, and nickel. A 2017 study by Longo and Rigler on historic samples of Johnson & Johnson baby powder ranging in production date over a span of many years showed over one-half (17 of 30) of Johnson's talcum powder product samples contained asbestos (Longo and Rigler, 2017). Talc containing asbestiform fibers (fibrous talc) was found in 15 of the 30 samples. A 2018 study by Longo and Rigler reported the presence of fibrous anthophyllite in products tested from 1978 as well as fibrous talc in both (Longo and Rigler, 2018). Additionally, I have reviewed the expert report of Drs. Longo and Rigler reporting that 37 of 56 historical talcum powder samples contained asbestos and 41 of the 42 samples tested contained fibrous talc[4].

Asbestos has long been recognized as a well-known carcinogen and exposure can cause lung disease, mesothelioma, and cancers of the lung, larynx, and ovary (IARC 1987, 2012). It is established that asbestos exposure can result in macrophage activation, inflammation, generation of reactive oxygen and reactive nitrogen species, tissue injury, genotoxicity, and resistance to programmed cell death (Aust, 2011; Hein, 2007; IARC, 2012; Jaurand, 1997; Wang, 1987). One of the direct mechanisms is through interactions between internalized fibers and components of mitosis, resulting in chromosomal alterations and abnormalities (Hesterberg et al., 1986; Wang et al., 1987; Yegles et al., 1993). IARC has classified asbestos as a known human carcinogen (Group

[2] Ex. 28, Hopkins Dep. (Aug. 16 & 17, 2018; Oct. 17, 2018; and Nov. 5, 2018); Blount, 1991; Paoletti, 1984.
[3] Ex. 47, Julie Pier Dep. (Sept. 12 & 13, 2018).
[4] Expert Report of William E. Longo, PhD and Mark W. Rigler, PhD (Nov. 14, 2018).

1). Human tumors resulting from asbestos exposure can be characterized by genetic and chromosomal alterations that lead to the inactivation of tumor-suppressor genes (IARC, 2012).

Talc not containing asbestiform fibers has been found by IARC to be a Group 2b or "possible" carcinogen (IARC, 2010). IARC has determined that fibrous talc or talc containing asbestiform fibers (talc occurring in a fibrous habit) is a carcinogen to humans (IARC, 2012).

Chromium and nickel are classified by IARC as Group 1, "carcinogenic to humans" (IARC, 2012). Cobalt is classified as Group 2B, "possibly carcinogenic to humans" (IARC, 2006). IARC defines possibly carcinogenic as "a positive association has been observed between exposure to the agent and cancer for which a causal interpretation has been considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence." Established carcinogenic mechanisms of chromium include DNA damage, mutation, genomic instability, and cell transformation (IARC, 2009). Similar mechanisms result from nickel exposure (IARC, 2012). Cobalt exposure has been to shown to cause increased production of reactive oxygen species and other inflammatory and proliferative changes (IARC, 2006).

I also reviewed Dr. Michael Crowley's report discussing the numerous fragrance chemicals added to talcum powder products. I am in agreement with Dr. Crowley's opinion that these chemicals contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products. The presence of these constituents as part of talcum powder products provides additional evidence of biological plausibility for talc and ovarian cancer. [5]

Carcinogenesis is a complex and dynamic process that occurs due to a combination of mutations, both genetic and acquired, in an individual along with other processes. Mutations arising from environmental sources have an additive, and possibly multiplicative effect toward ultimately causing carcinogenesis (Park, 2018; Vitonis, 2011; Wu, 2015). The presence of asbestos, nickel, and chromium, known carcinogens, in talcum powder products provides further support for the conclusion that talcum powder causes chronic inflammation.

[5] Expert Report of Michael Crowley, PhD (Nov. 12, 2018).

Based on these observations and lines of evidence, it is my opinion that talcum powder causes inflammation which initiates a biological response that includes oxidative stress, cell proliferation, inhibition of apoptosis, and genetic mutations which result in cancer development and progression. This process explains the biologically plausible mechanism for talcum powder products causing ovarian cancer.

VII. Conclusion

Based on my background, training, education, and experience as a geneticist assessing and weighing the totality of scientific evidence, my opinions may be summarized as follows:

1. Genetic mutations can be inherited or acquired. Both types are associated with cancer, including ovarian cancer.
2. Talcum powder products cause chronic inflammation.
3. Talcum powder product-induced inflammation causes damage to the DNA, genetic mutation, genomic instability, and cell transformation.
4. The properties of talcum powder products as inflammatory agents and the role of inflammation in triggering oxidative stress, activating cytokines, cell proliferation, DNA damage, and genetic mutations (such as SNVs) provide a biologically plausible mechanism for the carcinogenicity of talcum powder products.
5. Internalization of asbestiform fibers (including fibrous talc), cause DNA damage which provides a biologically plausible mechanism for the carcinogenicity of talcum powder products.
6. The presence of an inherited gene mutation, such as *BRCA1* or *BRCA2*, indicates a woman has an increased risk of ovarian cancer, but does not necessarily mean she will develop ovarian cancer.
7. Women with inherited gene mutations, such as *BRCA*, are at least as susceptible to other carcinogens as women without inherited gene mutations.

I reserve the right to supplement, revise, or amend this report should additional materials, including testimony, become available.

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Exhibit A

Shawn Edward Levy *Curriculum Vitae*

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Personal Statement

My group has been utilizing high performance genotyping and sequencing technologies for the past 15 years supporting a vast diversity of projects from plant and animal phylogenetic studies to translational and clinical based projects. We have several publications detailing our successes using variety of genomic technologies as well as in the field of bioinformatics research. As a post-doctoral fellow at Emory University I developed the first microarray designed to interrogate mitochondrial gene function. Upon joining the faculty at Vanderbilt University, I was responsible for the founding and development of the Vanderbilt Microarray Shared Resource (VMSR). From 2000 to 2009, the VMSR became an internationally recognized facility supporting a wide variety of genomic technologies from SNP profiling to gene expression analysis to next-generation sequencing. I joined the faculty of the HudsonAlpha Institute for Biotechnology in 2009 to develop the Genomic Services Laboratory (GSL). Since 2009 the GSL has supported more than 1,000 principle investigators from around the world, allowing me to collaborate and participate in a broad range of genomics projects with a particular focus on applying a diversity of genomic methods to understand complex conditions. We have had a particular focus on childhood and adult cancer as well as rare disease and degenerative diseases. Together, these efforts have resulted in more than 140 peer-reviewed publications of which I am an author or co-author. More than 150 additional publications that have included data from our laboratory as a service provider have also been published since 2009. Many of these publications involve translational research or describe the genetic underpinnings of rare or complex human disease. The diversity of projects and investigators we have worked with over the last 15 years have provided a dynamic and amazing experience to evolve our own research and technology development efforts.

Contributions to Science

The following five sections provide highlights to areas where my work has contributed to areas of science. Example publications are provided with each section and a full bibliography is provided at the end of the CV.

1. My scientific career has been a somewhat atypical in that I have spent the last 15 years focusing on the development and application of genomic and bioinformatic technologies and methods to support scientific investigation in a number of areas. While there have been substantial areas of focus, my laboratory does not operate under a single or specific biological area or hypothesis. Instead, we examine ways to improve the resolution and quality of results to answer complex questions, regardless of biological relationship. The publications below are examples of contributions to technical projects or large consortium projects with goals in the evaluation or improvement of techniques or technologies.

    a. Statnikov A, Aliferis, C, Tsamardinos, I, Hardin, D, and Levy, S. A comprehensive evaluation of multicategory classification methods for microarray gene expression cancer diagnosis. **Bioinformatics**, 2005. 21(5), p. 631-643. PMID:15374862.

b. The MicroArray Quality Control Consortium. The MicroArray Quality Control (MAQC) project shows inter- and intraplatform reproducibility of gene expression measurements. **Nature Biotechnology**, 2006. 24(9), p. 1151-1161. PMID:16964229.

c. The ENCODE Project Consortium. An integrated encyclopedia of DNA elements in the human genome. **Nature**. 2012. 489, 57-74. PMID: 22955616 PMCID: PMC3439153

d. The Sequence Quality Control (SEQC) Consortium. A comprehensive assessment of RNA-seq accuracy, reproducibility and information content by the Sequence Quality Control consortium. **Nature Biotechnology**. 2014. 32 (9), 915-925. PMID:25150835; PMCID:4167418.

2. One area of early focus of my career was the development and analysis of mouse models for mitochondrial disease, including the knock out of the Adenine Nucleotide Translocase 2 (Ant2) gene leading to a more complete understanding of the permeability transition. This work also discovered methods to alter the mitochondrial DNA in stem cells and supported the first mitochondrial DNA transfers by stem cells.

   a. Levy SE, Waymire, KG, Kim, YL, MacGregor, GR, and Wallace, DC, Transfer of chloramphenicol-resistant mitochondrial DNA into the chimeric mouse. **Transgenic Research**. 1999. 8(2), p. 137-145. PMID:10481313.

   b. Sligh JE, Levy SE, Waymire KG, Allard P, Dillehay DL, Nusinowitz S, Heckenlively JR, MacGregor GR, and Wallace DC. Maternal germ-line transmission of mutant mtDNAs from embryonic stem cell-derived chimeric mice. **Proc. of the Nat. Acad. of Sciences USA.** 2000. 97(26), p. 14461-14466. PMID:11106380; PMCID:18941.

   c. Kokoszka JE, Waymire, KG, Levy, SE, Sligh, JE, Cal, JY, Jones, DP, MacGregor, GR, and Wallace, DC, The ADP/ATP translocator is not essential for the mitochondrial permeability transition pore. **Nature**, 2004. 427(6973),p. 461-465. PMID:14749836.

   d. Picard M, Zhang J, Hanecock S, Derbeneva O, Golhar R, Golik P, O'Hearn S, Levy SE, Potluri P, Lvova M, Davila A, Lin CS, Perin JC, Rappaport EF, Hakonarson H, Trounce I, Procaccio V, and Wallace DC. Progressive increase in mtDNA 3243A>G heteroplasmy results in abrupt transcriptional remodeling. **Proc. of the Nat. Acad. of Sciences USA**. 2014. 111(38), E4033-E4042. PMID:25192935; PMCID:4183335.

3. A long-standing area of research interest is the genomic analysis of cancer, both childhood and adult. These efforts have included population-based studies and more directed research in specific cancer biology. These efforts have examined many cancer types including breast, lung, colon, and myeloid cancer.

   a. Smith JJ, Deane, NG, Wu, F, Merchant, NB, Zhang, B, Jiang, A, Lu, P, Johnson, JC, Schmidt, C, Edwards, CM, Eschrich, S, Kis, C, Levy, S, Washington, MK, Heslin, MJ, Coffey, RJ, Yeatman, TJ, Shyr, Y, and Beauchamp, RD, Experimentally Derived Metastasis Gene Expression Profile Predicts Recurrence and Death in Patients With Colon Cancer. **Gastroenterology**, 2009. PMID: 19914252 PMCID: PMC3388775.

   b. Powell AE, Wang Y, Li Y, Poulin EJ, Means AL, Washington MK, Higginbotham JN, Juchheim A, Prasad N, Levy SE, Guo Y, Shyr Y, Aronow BJ, Haigis KM, Franklin JL, and Coffey RJ. Lrig1, a pan-ErbB negative regulator, marks intestinal stem cells and acts as a tumor suppressor. **Cell**. 2012. 149(1), 146-158. PMID: 22464327 PMCID: PMC3563328.

   c. McDaniel JM, Varley KE, Gertz J, Savic DS, Roberts BS, Bailey SK, Shevde LA, Ramaker RC, Lasseigne BN, Kirby MK, Newberry KM, Partridge EC, Jones AL, Boone B, Levy SE, Oliver PG, Sexton KC, Grizzle WE, Forero A, Buchsbaum DJ, Cooper SJ, Myers RM. Genomic regulation of invasion by STAT3 in triple negative breast cancer. **Oncotarget**. 2017;8(5):8226-38. doi: 10.18632/oncotarget.14153. PubMed PMID: 28030809; PMCID: PMC5352396.

d. McKinney M, Moffitt AB, Gaulard P, Travert M, De Leval L, Nicolae A, Raffeld M, Jaffe ES, Pittaluga S, Xi L, Heavican T, Iqbal J, Belhadj K, Delfau-Larue MH, Fataccioli V, Czader MB, Lossos IS, Chapman-Fredricks JR, Richards KL, Fedoriw Y, Ondrejka SL, Hsi ED, Low L, Weisenburger D, Chan WC, Mehta-Shah N, Horwitz S, Bernal-Mizrachi L, Flowers CR, Beaven AW, Parihar M, Baseggio L, Parrens M, Moreau A, Sujobert P, Pilichowska M, Evens AM, Chadburn A, Au-Yeung RK, Srivastava G, Choi WW, Goodlad JR, Aurer I, Basic-Kinda S, Gascoyne RD, Davis NS, Li G, Zhang J, Rajagopalan D, Reddy A, Love C, Levy S, Zhuang Y, Datta J, Dunson DB, Dave SS. The Genetic Basis of Hepatosplenic T-cell Lymphoma. **Cancer Discov**. 2017;7(4):369-79. doi: 10.1158/2159-8290.CD-16-0330. PubMed PMID: 28122867; PMCID: PMC5402251.

4. My laboratory has had the opportunity to collaborate with a number of outstanding investigators in the genetics analysis of complex neurological conditions, including autism, schizophrenia and bipolar disorders as well as ALS. We contributed significantly to the discovery of the association of de-novo rather than Mendelian mutations in these conditions, particularly in schizophrenia.
   a. Xu B, Roos JL, Dexheimer P, Boone B, Plummer B, Levy S, Gogos JA, Karayiorgou M. Exome sequencing supports a de novo mutational paradigm for schizophrenia. **Nature Genetics**. 2011. 43(9), 864-868. PMID: 21822266. PMCID: PMC3196550.
   b. Neale BM, Kou Y, Liu L, Ma'ayan A, Samocha KE, Sabo A, Lin CF, Stevens C, Wang LS, Makarov V, Polak P, Yoon S, Maguire J, Crawford EL, Campbell NG, Geller ET, Valladares O, Shafer C, Liu H, Zhao T, Cai G, Lihm J, Dannenfelser R, Jabado O, Peralta Z, Nagaswamy U, Reid JG, Newsham I, Wu Y, Lewis L, Han Y, Muzny D, Voight BF, Lim E, Rossin E, Kirby A, Flannick J, Fromer M, Shakir K, Fennell T, Garimella K, Boyko C, Gabriel S, dePristo M, Wimbish JR, Boone BE, Levy SE, Betancur C, Sunyaev S, Boerwinkle E, Buxbaum JD, Cook EH, Devlin B, Gibbs R, Roeder K, Schellenberg GD, Sutcliffe JS, and Daly MJ. Patterns and rates of exonic de novo mutations in autism spectrum disorders. **Nature**. 2012. 485(7397), 242-245. PMID: 22495311 PMCID:PMC3613847.
   c. Xu B, Ionita-Laza I, Roos JL, Boone B, Woodrick S, Sun Y, Levy S, Gogos JA, and Karayiorgou M. De novo gene mutations highlight patterns of genetic and neural complexity in schizophrenia. **Nature Genetics**. 2012. 44(12), 1365-1369. PMID: 23042115 PMCID: PMC3556813.
   d. Cirulli, ET, Lasseigne, BN, Petrovski, S, Sapp, PC, Dion, PA, Leblond, CS, Couthouis, J, Lu, Y-F, Wang, Q, Krueger, BJ, Ren, Z, Keebler, J, Han, Y, Levy, SE, Boone, BE, Wimbish, JR, Waite, LL, Jones, AL, Carulli, JP, Day-Williams, AG, Staropoli, JF, Xin, WW, Chesi, A, Raphael, AR, McKenna-Yasek, D, Cady, J, Vianney de Jong, JMB, Kenna, KP, Smith, BN, Topp, S, Miller, J, Gkazi, A, Consortium, FS, Al-Chalabi, A, van den Berg, LH, Veldink, J, Silani, V, Ticozzi, N, Shaw, CE, Baloh, RH, Appel, S, Simpson, E, Lagier-Tourenne, C, Pulst, SM, Gibson, S, Trojanowski, JQ, Elman, L, McCluskey, L, Grossman, M, Shneider, NA, Chung, WK, Ravits, JM, Glass, JD, Sims, KB, Van Deerlin, VM, Maniatis, T, Hayes, SD, Ordureau, A, Swarup, S, Landers, J, Baas, F, Allen, AS, Bedlack, RS, Harper, JW, Gitler, AD, Rouleau, GA, Brown, R, Harms, MB, Cooper, GM, Harris, T, Myers, RM, Goldstein, DB. Exome sequencing in amyotrophic lateral sclerosis identifies risk genes and pathways. **Science**. 2015. Feb 19. pii: aaa3650. [Epub ahead of print] PubMed PMID: 25700176.

5. My laboratory has played a significant role in the discovery of the causative mutations of a number of rare but significant human diseases, particularly in the field of pediatric nephrology in collaboration with Friedhelm Hildebrandt at Harvard University. These studies applied genomic technologies to better characterize and in some cases diagnose or discover the causative mutation for severe phenotypes or disease.
   a. Otto EA, Hurd TW, Airik R, Chaki M, Zhou W, Stoetzel C, Patil SB, Levy S, Ghosh AK, Murga-Zamalloa CA, van Reeuwijk J, Letteboer SJF, Sang L, Giles RH, Liu Q, Coene KLM, Estrada-

Cuzcano A, Collin RWJ, McLaughlin HM, Held S, Kasanuki JM, Ramaswami G, Conte J, Lopez I, Washburn J, MacDonald J, Hu, J, Yamashita Y, Maher ER, Guay-Woodford L, Neumann HPH, Obermuller H, Koenekoop RK, Bergmann C, Bei X, Lewis RA, Katsanis N, Lopes V, Williams DS, Lyons RH, Dang CV, Brito DA, Dias MB, Zhang X, Nurnberg G, Nurnberg P, Pierce E, Jackson P, Antignac C, Saunier S, Roepman R, Dollfus H, Khanna H, and Hildebrandt F. Candidate exome capture identifies mutation of SDCCAG8 as the cause of a retinal-renal ciliopathy. **Nature Genetics**, 2010. 42(10), 840-850 PMID: 20835237 PMCID: PMC2947620.

b. Rademakers R, Baker M, Nicholson AM, Rutherford NJ, Finch N, Soto-Ortolaza A, Lash J, Wider C, Wojtas A, DeJesus-Hernandez M, Adamson J, Kouri N, Sundal C, Shuster EA, Aasly J, MacKenzie J, Roeber S, Kretzschmar HA, Boeve BF, Knopman DS, Petersen RC, Cairns NJ, Ghetti B, Spina S, Garbern J, Tselis AC, Uitti R, Das P, Van Gerpen JA, Meschia JF, Levy S, Broderick DF, Graff-Radford N, Ross OA, Miller BB, Swerdlow RH, Dickson DW, Wszolek ZK.Mutations in the colony stimulating factor 1 receptor (CSF1R) cause hereditary diffuse leukoencephalopathy with spheroids. **Nature Genetics**. 2011. 44(2), 200-205. PMID: 22197934 PMCID: PMC3267847.

c. Fiskerstrand T, Arshad N, Haukanes BI, Tronstad RR, Pham KDC, Johansson S, Håvik B, Tønder SL, Levy SE, Brackman D, Boman H, Biswas KH, Apold J, Hovdenak N, Visweswariah SS, and Knappskog PM. Familial Diarrhea Syndrome Caused by an Activating GUCY2C Mutation. **New England Journal of Medicine**. 2012. 366(17), 1586-1595. PMID: 22436048.

d. Carlson J, Scott LJ, Locke AE, Flickinger M, Levy S, Myers RM, Boehnke M, Kang HM, Li JZ, Zöllner S. Extremely rare variants reveal patterns of germline mutation rate heterogeneity in humans. **bioRxiv**. 2017:108290.

e. Chao HT, Davids M, Burke E, Pappas JG, Rosenfeld JA, McCarty AJ, Davis T, Wolfe L, Toro C, Tifft C, Xia F, Stong N, Johnson TK, Warr CG, Undiagnosed Diseases N, Yamamoto S, Adams DR, Markello TC, Gahl WA, Bellen HJ, Wangler MF, Malicdan MC. A Syndromic Neurodevelopmental Disorder Caused by De Novo Variants in EBF3. **Am J Hum Genet**. 2017;100(1):128-37. doi: 10.1016/j.ajhg.2016.11.018. PubMed PMID: 28017372; PMCID: PMC5223093.

Education

College
University of New Hampshire: BS, 1994 (Biochemistry, Microbiology)
GPA 3.37
Honors Graduate, Dean's list.

Graduate School
Emory University: PhD, 2000, (Biochemistry)
GPA 3.75
Thesis title: "Genetic Alteration of the Mouse Mitochondrial Genome and Effects on Gene Expression."
Thesis advisor: Professor Douglas C. Wallace

Post-Graduate Training
Emory University, Douglas C. Wallace, March 2000-July 2000

Academic Appointments

Research Assistant Professor, Department of Molecular Physiology and Biophysics,
Vanderbilt University Medical Center, Nashville, TN, July 2000-June 2003

Adjunct Faculty, Graduate training program, Department of Biomedical Informatics, Vanderbilt University Medical Center, Nashville, TN, January 2001-June 2003

Director, Vanderbilt Microarray Shared Resource, Vanderbilt University Medical Center, Nashville, TN, July 2000-August 2009

Assistant Professor, Department of Biomedical Informatics, Vanderbilt University Medical Center, Nashville, TN, July 2003-August 2009. *(Primary Appointment)*

Assistant Professor, Department of Molecular Physiology and Biophysics, Vanderbilt University Medical Center, Nashville, TN, July 2003-August 2009 *(Secondary Appointment)*

Adjunct Associate Professor, Department of Biomedical Informatics, Vanderbilt University Medical Center, Nashville, TN, August 2009-Present

Adjunct Associate Professor, Department of Epidemiology, University of Alabama-Birmingham, Birmingham, AL October 2010-Present.

Adjunct Assistant Professor, Department of Genetics, University of Alabama-Birmingham, Birmingham, AL October 2010-Present.
Adjunct Associate Professor, Department of Biological Sciences, University of Alabama-Huntsville, Huntsville, AL January 2014-Present.

Faculty Investigator, HudsonAlpha Institute for Biotechnology, Huntsville, AL, August 2009-Present

Executive Director, HudsonAlpha Clinical Services Laboratory, LLC, Huntsville, AL, December 2014-Present

Professional Organizations

American Medical Informatics Association, Co-chair, Genomics Working Group (2006-2007)
Association of Biomedical Resource Facilities
American Association for the Advancement of Science
American Association for Cancer Research
American Society for Human Genetics

Professional Activities

Intramural-University
Vision 2020 Personalized Medicine Committee-Task Force 3 (2009)

Intramural-Departmental
Department of Biomedical Informatics Academic Progress Committee (2005-2007)
Department of Biomedical Informatics Curriculum Committee (2007-2009)

Intramural-Center Affiliations
Vanderbilt-Ingram Cancer Center, Associate Member (2000-2009)
Vanderbilt Diabetes Research and Training Center, Member (2000-2009)

Vanderbilt Digestive Disease Research Center, Member (2003-2009)
Vanderbilt Institute of Chemical Biology, Member (2004-2009)

Extramural-Journal Review
- Reviewer- Arteriosclerosis, Thrombosis and Vascular Biology (2001-present)
- Reviewer-Bioinformatics (2001-present)
- Reviewer-Journal of Biological Chemistry (2002-present)
- Reviewer-Neuropsychopharmacology (2003-present)
- Reviewer-Kidney International (2003-present)
- Reviewer-Circulation Research (2003-present)
- Reviewer-Proceedings of the National Academy of Sciences (2004-present)
- Reviewer-Mitochondrion (2004-present)
- Reviewer-Molecular Nutrition and Food Research (2005-present)
- Reviewer-Pattern Recognition Letters (2006-present)
- Reviewer-PLOS-Genetics (2006-present)
- Reviewer-Physiological Genomics (2008-present)
- Reviewer-Genome Biology (2008-present)

Extramural-Editorial
- Member, Editorial Board- Journal of the American Informatics Association (2005-2007)

Extramural-Grant Study Section
- Reviewer- Alzheimer's Association (2002-present).
- NIDDK study section ZDK1 GRB-6 "Digestive Disease Research Development Centers" December 2002.
- NIDDK study section ZDK1 GRB-6 "Digestive Disease Research Development Centers" April 2004.
- NCI study section ZCA1 SRRB-C "Innovative Technologies for the Detection of Cancer" July 2004.
- NLM special study section-P41 Biomedical Informatics Resource Grants, April 2005.
- NLM special emphasis panel ZLM1 HS RO1, July 2005
- NIH CSR shared equipment study section ZRG1 GGG-T (30, 31), November 2005.
- DOD Ovarian Cancer Review Panel OC-2, August 2006
- NIH Special Emphasis Panel ZRG1 GGG-T Genomics and Genetics Shared Instrumentation, October 2006.
- NCI study section ZCA1 SRRB-U Development of Advanced Genomic Characterization Technologies, November 2006.
- NIDDK DK-06-017 "Silvio O. Conte Digestive Diseases Research Core Centers P30", June 2007.
- NIH Special Emphasis Panel ZRG1 GGG-A (30) - S10s genomics and proteomics shared instrumentation, July 2007.
- NIH Special Emphasis Panel ZRG1 GGG-B (30) - S10s genomics and proteomics shared instrumentation, September 2008.
- NIAAA Special Review Panel ZAA1-GG-01, November 2008
- NIH Special Emphasis Panel ZRG1 GGG-A (30) – Genes Genomes and Genetics instrumentation, October 2010.
- NIH Study Section 2011/05 GHD-Genetics of Health and Disease Study Section, February 2011.
- NIGRI Study Section 2012/05 ZHG1 HGR-P (M1) 1-H3 AFRICA Initiative, March 2012.

Extramural-Other Review

- Reviewer, American Association for the Advancement of Science Research Competitive Service-*Microarray Facilities for the Vermont Genetics Network*. April 2002.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Michigan Core Technology Alliance*. April 2003.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Michigan Core Technology Alliance*. April 2004.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. January 2007.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. March 2008.
- Reviewer, American Association for the Advancement of Science Research Competitive Service- *Review of Washington State Life Sciences Discovery Fund* June 2008.
- Reviewer, American Association for the Advancement of Science Research Competitive Service- *Review of Missouri Life Sciences Research Board* October 2008
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. June 2009.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. May 2010.
- Reviewer, American Association for the Advancement of Science Research Competitive Service-*External Review of the Rhode Island EPScOR*. September 2011.

Extramural-Advisory

- Member, Scientific Advisory Board, NuGen Technologies, Inc, San Carlos, CA, October 2003-December 2010.
- Member, Scientific Advisory Board, Genome Quebec Innovation Centre, Montreal, Quebec, 2008-2011.
- Member, Scientific Advisory Board, Genomic Explorations Inc, Memphis, TN, 2006-present.
- Member, Scientific Advisory Board, Rubicon Genomics, Ann Arbor, MI 2013-present.
- Chairman, Scientific Advisory Board, RainDance Technologies (BioRad), Billerica, MA 2015-present.

Honors and Awards

- Scholar Athlete, University of New Hampshire, 1993-1994.
- Dean's list, University of New Hampshire, 1992-1994.
- Career Development Award, SPORE in Gastrointestinal Cancer 2004-2005
- Co-Chair, Genomics Working Group of the American Medical Informatics Association 2006-2007.

Teaching Activities

Graduate School Courses as Course Director

BMIF 310-Foundations of Bioinformatics and Computational Biology, 28 lectures, Spring 2004
BMIF 311-Introduction to Systems Biology, 28 lectures, Spring 2009. *This course was a newly developed course for 2009.*

Graduate School Courses as Lecturer

MPB 322-Regulation of Gene Expression, 3 lectures, Spring 2002
MPB 322-Regulation of Gene Expression, 2 lectures, Spring 2003
MPB 322-Regulation of Gene Expression, 3 lectures, Spring 2004

IGP 301-Methodology, 1 lecture, Fall 2004
IGP 301-Methodology, 1 lecture, Fall 2005
IGP 301-Methodology, 1 lecture, Fall 2006
MIM 351-Functional Genomics and Proteomics, 2 lectures, Spring 2006
BMIF 310-Foundations of Bioinformatics and Computational Biology, 7 lectures, Fall 2007
BMIF 310-Foundations of Bioinformatics and Computational Biology, 7 lectures, Fall 2008
BMIF 310-Foundations of Bioinformatics and Computational Biology, 4 lectures, Fall 2009
BMIF 310-Foundations of Bioinformatics and Computational Biology, 4 lectures, Fall 2010
BMIF 310-Foundations of Bioinformatics and Computational Biology, 1 lecture, Fall 2011

Research Supervision

Ph.D. Thesis Committee Member
Stephen VonStetina-Vanderbilt University (2001-2005)
Laura Wilding-Vanderbilt University (2003-2007)
Alex Statnikov-Vanderbilt University (2005-2008)
Alisha Russell-Vanderbilt University (2006-2010)
Mawuli Nyaku-University of Alabama-Birmingham (2010-2014)

M.S. Thesis Committee Member
Alex Statnikov (2003-2005)
Joel Parker (2000-2002)

Student Mentorship
Shristi Shrestha, PhD student (2014-present)
Nripesh Prasad, PhD student (2010-2014)
Sidd Pratrap MS student (2005-2007)
Current position: Director of Bioinformatics, Meharry Medical College, Nashville, TN

Fellow Mentorship
Lewis Frey, PhD (2004-2006)
Current position: Assistant Professor, Department of Biomedical Informatics, University of Utah, Salt Lake City, UT.

Patents Awarded

Multiplex spatial profiling of gene expression
US 7,569,392 B2

Research Support

ACTIVE

NIH RFA-HG-16-011 (Cooper/Barsh/Korf) 06/01/2017 – 05/31/2021 0.60 calendar months
$2,840,944
Clinical sequencing across communities in the Deep South

This proposal outlines an important study to apply WGS to diagnose neonates with rare disorders, increase participation of individuals from underrepresented racial/ethnic groups in genomics clinical trials, provide educational materials appropriate to diverse audiences, equip non-genetics healthcare providers to return WGS results, assess the impact of WGS testing and

results, and engage a broad community to implement safer, more effective, and more equitably distributed genomic medicine.

1U24HD090744-01 (Levy/Zhang) 09/23/2016 – 06/30/2019 2.40 calendar months
NIH/NICHD $6,212,400
Characterizing pediatric genomes through an optimized sequencing approach

Understanding the fundamental genetic changes associated with structural birth defects and childhood cancers is an important step in developing tools to allow more advanced prediction, treatment and prevention of these devastating conditions. We propose to combine the resources of two world-class centers to support researchers in their investigations of the genetics of birth defects and childhood cancers. This centralized resource will provide researchers with the tools and support necessary to advance our understanding and drive us closer to curing or preventing these diseases.

5UL1TR001417-02 (Kimberly) 08/18/2015 - 03/31/2019 0.60 calendar months
NIH/NCATS $83,644
UAB Center for Clinical and Translational Science (CCTS)

The UAB CCTS will enhance human health by driving scientific discovery and dialogue across the bench, bedside and community continuum. The CCTS support this overall mission in a highly integrative network of relationships. Success in creating such an environment is dependent upon success in achieving five strategic priorities: 1) enhancing research infrastructure; 2) promoting investigator education, training and development; 3) accelerating discovery across the T1 interface; 4) expanding value-added partnerships; and 5) building sustainability.

HHSN2722012000231 (Creech) 09/01/2015 – 09/30/2018 0.24 calendar months
NIH/NIAID $555,660
Influenza A/H7N9 Vaccine Administered with/without AS03 Adjuvant: Standard and Systems Biology

HudsonAlpha will receive human RNA samples from Vanderbilt University Medical Center. RNA-sequencing will be performed per specifications provided in the clinical protocol and clarified in the manual of procedures. We will perform all necessary experiments, including quality control assays. Once sequencing data are obtained, these FastQ/BAM files will be transferred to Vanderbilt University Medical Center and to the DMID Statistics and Data Coordinating Center (SDCC) for data analysis.

HHSN2722012000231 (Creech) 09/01/2015 – 09/30/2018 0.24 calendar months
NIH/NIAID $56,630
Sub-study for DMID 10-0074

HudsonAlpha will receive human RNA samples from Vanderbilt University Medical Center. RNA-sequencing will be performed per specifications provided in the clinical protocol and clarified in the manual of procedures. We will perform all necessary experiments, including quality control assays. Once sequencing data are obtained, these FastQ/BAM files will be transferred to Vanderbilt University Medical Center and to the DMID Statistics and Data Coordinating Center (SDCC) for data analysis.

6U19CA179514-05 (Coffey) 09/01/2013 - 08/31/2018 0.24 calendar months
NIH/NCI $39,254
Secreted RNA during CRC progression biogenesis function and clinical markers

Dr. Levy's laboratory will fully support RNA sequencing on 48-74 samples per year prepared from either total RNA or microRNA at the HudsonAlpha Institute for Biotechnology. Dr. Levy's laboratory will provide all required reagents, personnel and basic analysis support for the

proposed sequencing studies during years 1-5 of the project period.

5U01MH105653-03 (Boehnke) 09/19/2014 - 05/31/2018 0.60 calendar months
NIH/NIMH $23,557
Whole Genome Sequencing for Schizophrenia and Bipolar Disorder in the GPC

Dr. Levy will participate in weekly conference calls and several yearly face-to-face meetings to help make this project successful. Any new improvements in sequencing technology, data analysis and data interpretation that are developed and/or applied at HudsonAlpha will be made immediately available to this project.

3P30CA013145-44S4 (Partridge) 04/01/2017 – 03/31/2018 0.60 calendar months
NIH/NCI $113,863
Comprehensive Cancer Center Core Support Grant

Dr. Myers, President and Science Director of HudsonAlpha Institute for Biotechnology, will be part of the director's council. The director's council meets on a monthly basis to advise the director on all major decisions regarding the UAB-CCC, its organization, planning and evaluation and to approve new developmental research programs and review program leaderships. In addition, Dr. Myers will co-lead UAB-CCC's Experimental Therapeutics program. Drs. Absher and Levy will be co-leaders of the Cancer Cell Biology Program and Cancer Control & Population Sciences Program. Dr. Cooper is an Associate Scientist in Experimental Therapeutics program. They will consult investigators in study design and analysis related to genomic data.

4UM1HG007301-04 (Cooper/Myers) 06/14/2013-05/31/2018(NCE) 0.60 calendar months
NIH/NHGRI $1,536,927
Genomic Diagnosis in Children with Developmental Delay

The goal of this project is to address technological, analytical, and ethical challenges that prevent optimal use of DNA sequencing to improve treatment of diseases and life planning for patients and their families. We are applying next-generation DNA sequencing to meet the diagnostic needs of children with developmental delay, intellectual disability and related health problems.

Genomic Services Lab Director 4.80 calendar months

In addition to the projects listed above, Dr. Levy, as the Director of the Genomic Services Laboratory (GSL), is involved in the development and application of genomic and bioinformatic technologies and methods to support scientific research. These activities, along with fee-for-service projects, change often making it difficult to assign a precise percent effort to individual projects. Dr. Levy has reviewed his GSL obligations and confirms that the aggregate effort on all GSL projects at any given time does not exceed 40% (4.80 calendar months) of institutional effort.

PENDING

COMPLETED

US MED Research ACQ Activity (PI: Richard M. Myers)
9/16/10 - 8/31/15
Direct Costs for current year: $2,150,777
Shawn E. Levy effort: 33% effort [4.0 cal. mos.]
Title: Global genomic analysis of prostate, breast and pancreatic cancer

The goals of this study are to provide an unprecedented comprehensive view of the molecular pathogenesis of prostate, breast, and pancreatic cancer, as well as the differential response to treatments in breast cancer. We will use next-generation DNA sequencing to measure mRNA, microRNA, DNA methylation, DNase hypersensitivity sites, histone modifications, and sites of transcription factor occupancy in tumors and matched non-tumor tissues for these three cancers. No budgetary or scientific overlap.
Role: Co-investigator

NIH (PIs of Collaborative R01: Richard M. Myers and Michael Boehnke)
8/30/11 - 6/30/14
Direct costs for current year for HudsonAlpha portion: $1,855,348
Shawn E. Levy effort: 20% [2.4 cal. mos.]
Title: Whole Genome and Exome Sequencing for Bipolar Disorder
In this collaborative R01 grant, performed jointly with Dr. Michael Boehnke and colleagues at the University of Michigan, we are performing a detailed genetic analysis of bipolar disorder. We are using ultrahigh-throughput sequencing to determine the deep whole genome sequences from 1,000 individuals with bipolar disorder and 1,000 control individuals without the disorder.

NIH/NIAMS 1 R01 AR057202 (PI: Louis Bridges)
4/1/09 - 3/31/14
Direct Costs for current year for Myers/Absher portion: $298,704
Shawn E. Levy effort: 5% effort [0.60 cal mos.]
Title: Genome Wide Association Study in African-Americans with Rheumatoid Arthritis
In this study, the Myers lab and Devin Absher and his lab at HudsonAlpha are collaborating with Dr. Lou Bridges and his colleagues at the School of Medicine at the University of Alabama in Birmingham to perform a genome-wide genetic association study of rheumatoid arthritis in African Americans. No budgetary or scientific overlap.
Role: Co-investigator

NHGRI P50 HG02568 (PI: David Kingsley)
4/19/02 - 5/31/12
Direct costs for current year: $701,981
Shawn E. Levy effort: 10% effort [1.2 cal. mos.]
Title: Center for Vertebrate Diversity
The continuation of this Center of Excellence in Genome Science (CEGS) has broad goals to understand the genetic basis for the striking biological diversity seen in vertebrate animals. We use genetics, genomics, molecular biology and computational tools to study this problem, focusing on the three-spined stickleback fish. HudsonAlpha performs many of the genomic experiments for this project, including genomic DNA sequencing, cDNA sequencing, BAC map construction, and genotyping.
Role: Co-investigator

5 U54 HG004576-03 (Myers) 10/01/2007 – 09/30/2011 1.20 calendar
NIH/NHGRI $3,985,643
“Global Annotation of Regulatory Elements in the Human Genome”

This project, which is a collaboration between the Myers group at HudsonAlpha and Barbara Wold’s group at Caltech, along with contributions from Wing Wong, Arend Sidow, Serafim Batzoglou and Gavin Sherlock at Stanford, is part of the ENCODE Project, whose goals are to identify and understand the roles of all the functional elements throughout the entire human

genome. Our contributions are to identify transcription factor binding sites, assess the methylation status and measure RNAs with next-gen sequencing.
Role: Co-investigator

1 RC1 DK086594-01 (Southard-Smith)
09/30/2009 – 09/29/2011 0.60 calendar months
NIH $240,970
"Gene Networks in Neutral Crest-derived Innervation of the Lower Urinary Tract"
The studies proposed aim to identify essential genes that control development of nerves in the lower urinary tract that regulate bladder control and sexual function. These studies are important for understanding how these nerves normally develop and for deriving technologies that will restore neural function in urogenital birth defects or after pelvic surgery. This proposal is in response to the broad Challenge grant area of Regenerative medicine and meets multiple needs for basic research in development lower urinary tract innervation.
Role: Co-investigator

5 P30 CA68485-13 (Pietenpol)

09/28/2004 - 08/31/2009 1.80 calendar months
NIH/NCI $3,553,801
"Cancer Center Support Grant"

As part of the Vanderbilt Ingram Cancer Center's support grant, the goal of the Microarray Core is to provide genome-scale expression profiling technologies as well as analysis and informatics support to researchers who are members of the center.

5 P30DK058404-07 (Polk)
08/30/2007 - 05/31/2012 1.20 calendar months
NIH/NIDDK $727,500
"Molecular and Cellular Basis of Digestive Diseases"

As part of a center grant, the goal of the Microarray Core in the Vanderbilt Digestive Diseases Center is to provide support for the use of genome-scale expression profiling technologies to researchers involved in digestive disease-related research.
Role: Core Leader

5 P60 DK20593-31 (Powers)
06/01/2007 - 03/31/2012 0.24 calendar months
NIH/NIDDK $1,487,659
"Diabetes Research and Training Center"

As part of a center grant, the goal of the Microarray and Bioinformatics Core in the Diabetes Research and Training Center is to provide support for the use of genome-scale expression profiling technologies to researchers involved in DRTC-related research.
Role: Core Leader

2 R01 CA064277-10A1 (Zheng)
08/05/2008 - 05/31/2013 0.24 calendar months
NIH/NCI $324,917
"Shanghai Breast Cancer Study"

This proposal is aimed at the development of novel algorithms for the analysis of high-dimensionality data towards to the discovery of causal markers and mechanisms.
Role: Co-investigator

5 U24 DK58749-03 (George)
09/30/00 - 08/31/03 1.2 calendar months
NIH/NIDDK
Vanderbilt NIDDK Biotechnology Center
Purpose: The goal of this proposal was the establishment of a Biotechnology Center for the support of genomic studies of interest to investigators funded by the NIDDK. Microarray technologies and related informatics were central to the efforts.
Role: Co-investigator

VUMC Discovery Grant 540 (Levy)
01/01/02 - 12/31/03 1.2 calendar months
VUMC Internal Grant $50,000
Gene Expression Analysis of Colon Cancer
The goal of this proposal was the development of an integrated RNA and protein expression profile for colon cancer utilizing microarray and high-resolution protein profiling technologies. These profiles were useful in designing and developing both technological and informatic platforms for the combined analysis of protein and genetic profiles of cancer.
Role: Principle Investigator

ACS IRG-58-009-46 (Levy) 07/01/03 - 06/30/04
ACS/VICC
Simultaneous profiling of protein and RNA expression by mass spectrometry in intact tissue sections.
The goal of this proposal is to develop a novel technology platform that facilitates the simultaneous profiling of protein and RNA species in intact tissue samples while reporting spatial position. This will provide an unprecedented resolution to examine the biology of tumor samples and host-tumor interactions.
Role: Principle Investigator

1 R21 NS043581-01A1 (McDonald)
12/01/02 - 11/30/04
NIH/NINDS
Gene Discovery in a Putative Mouse Model of ADHD
In this proposal, microarray technology will be used to examine differential gene expression in the mouse model of ADHD, providing a rare opportunity to discover genes downstream of TRß activity that are able to produce all of the core symptoms and many adjunct features of ADHD.
Role: Co-investigator

1 U01 DK063587-01 (Hayward)
09/30/02 - 06/30/05
NIH/NIDDK
Genetic Markers of Transition Zone Hyperplasia
The goals of this proposal are the identification of biomarkers for prostate hyperplasia through the use of high-density microarray studies on novel models of prostate disease.
Role: Co-investigator

W81XWH-04-1-0626 (Levy S)
07/15/04-07/14/06
Department of Defense
Simultaneous profiling of protein and RNA expression by mass spectrometry in intact breast tissue sections.
The goal of this proposal is to continue the development of a novel technology platform that facilitates the simultaneous profiling of protein and RNA species in intact tissue samples while reporting spatial position. This proposal will specifically fund the optimization of this technology for the analysis of breast tissue samples.
Role: Principle Investigator

5 P01 HL6744-04 (Hawiger J)
12/01/01-11/30/06
NIH/NHLBI
Functional Genomics of Inflammation
As part of a Program Project Grant, the goal of the Microarray Core in the Functional Genomics of Inflammation program project is to provide genome-scale expression profiling technologies to researchers involved in the program.
Role: Core Leader

1 R01 DK068261-01 (Nagy T)
07/01/04-06/30/07
NIH/NIDDK (subcontract with UT)
Antipsychotic Drug-induced Weight Gain
The goal of this study is to understand the actions of antipsychotic drugs as they alter body weight. In this short subcontract with the University of Alabama, an animal model system used to study the molecular effects of selected drugs will be analyzed using genomic profiling techniques.
Role: Principal Investigator-subcontract

5 P60 DK20593-27 (Powers A)
07/20/02-03/31/07
NIH/NIDDK
Diabetes Research and Training Center-Microarray and Bioinformatics Core
As part of a center grant, the goal of the Microarray Core in the Diabetes Research and Training Center is to provide support for the use of genome-scale expression profiling technologies to researchers involved in DRTC-related research.
Role: Core Leader

5 P50 CA95103-04 (Coffey RJ)
09/24/02-04/30/07
NIH/NCI
SPORE in GI Cancer
This study will investigate the molecular features of tumors in GI cancer and provide full support for genomic profiling projects as part of the overall SPORE program.
Role: Core Leader

U24 CA126563 (Myers)
09/28/06 – 08/31/10
NIH/NCI
“The HudsonAlpha Cancer Genome Characterization Center

We are characterizing tumors and matched non-tumor samples for copy number variations throughout the human genome as part of The Cancer Genome Atlas project, a trans-NIH initiative aimed at learning all the genetic and genomic changes associated with cancer. We use a whole-genome genotyping method to assay more than 1 million SNPs throughout the genome.
Role: Co-investigator

1 RC1 HL100016-01 (Schey)
09/30/09 – 09/29/11
NIH-ARRA Funding
"Proteome and Transcriptome Markers of Hypertension in Urine and Plasma Exosomes"
The goal of the proposed research is to develop a novel method for discovery of molecular markers of disease that circumvents existing obstacles. Through analysis of proteins and RNA found in lipid particles isolated from blood and urine, new markers of disease will be discovered that improve diagnosis, prognosis, and prediction of response to therapy; that is, improve personalized medicine. The new methodology will be applied to reveal biomarkers of salt-sensitivity and therapeutic response in hypertensive subjects.
Role: Co-investigator

Publications

162 peer-reviewed publications with a total of 23,891 citations (*as of October 2018*)**.**

A full publication and patent listing can be accessed via a public Google Scholar profile at:
http://scholar.google.com/citations?user=xeKJAZ0AAAAJ
As well as at NCBI:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1BODvQqGn4iAa/bibliography/43127950/public/

Articles in refereed journals

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Exhibit B

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Depositions

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Expert Reports

Expert Report of Michael Crowley, PhD (Nov. 15, 2018)

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Documents Produced

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